

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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|---------------------------------|---|---------------------------|
| IN RE: DIET DRUGS (PHENTERMINE/ |) | |
| FENFLURAMINE/DEXFENFLURAMINE) |) | MDL NO. 1203 |
| PRODUCTS LIABILITY LITIGATION |) | |
| |) | |
| THIS DOCUMENT RELATES TO: |) | |
| |) | |
| SHEILA BROWN, et al. |) | CIVIL ACTION NO. 99-20593 |
| v. |) | |
| |) | |
| AMERICAN HOME PRODUCTS |) | 2:16 MD 1203 |
| CORPORATION |) | |

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

Bartle, C.J.

June 4, 2010

Faye E. Cobb ("Ms. Cobb" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. L. C. Cobb, Ms. Cobb's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In January, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Arnold B. Meshkov, M.D., F.A.C.C. Based on an echocardiogram dated February 4, 2002,⁴ Dr. Meshkov attested in Part II of Ms. Cobb's Green Form that she suffered from severe mitral regurgitation and

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. According to Dr. Meshkov, the echocardiogram on which he based his Green Form responses was performed on February 5, 2002. The report of claimant's echocardiogram, however, reflects that the procedure was performed on February 4, 2002. In addition, in a subsequent letter to claimant's counsel, Dr. Meshkov referred to the date of the echocardiogram as February 4, 2002.

a reduced ejection fraction in the range of 50% to 60%.⁵ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$486,424.⁶

In the report of claimant's echocardiogram, the reviewing cardiologist, R. Douglas Ensley, M.D., stated that claimant had "moderate to severe mitral regurgitation." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Ensley also estimated claimant's ejection fraction to be "50% to 60%." An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. IV.B.2.c.(2)(b)iv).

In September, 2005, the Trust forwarded the claim for review by Alan Bier, M.D., F.A.C.P., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Bier concluded that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction in the range

5. Dr. Meshkov also attested that claimant suffered from moderate aortic regurgitation and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). A reduced ejection fraction is one of the complicating factors needed to qualify for a Level II claim.

of 50% to 60% because claimant's echocardiogram demonstrated an ejection fraction between "65%-70%." In support of this conclusion, Dr. Bier explained that "[t]he left ventricular contraction is vigorous and symmetrical in all projections. Clearly greater than 60%."⁷

Based on the auditing cardiologist's finding that claimant did not have a reduced ejection fraction, the Trust issued a post-audit determination denying Ms. Cobb's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁸ In contest, claimant argued that there was a reasonable medical basis for Dr. Meshkov's Green Form representation that Ms. Cobb suffered from a reduced ejection fraction. In support, claimant submitted a letter from Dr. Meshkov wherein he stated that he again reviewed Ms. Cobb's medical records and February 4, 2002 echocardiogram and confirmed that her "ejection fraction is in the range of 50 to 60%, and in fact the ejection fraction is most likely closer to 50% than 60%." Dr. Meshkov explained that an

7. Dr. Bier also determined that claimant had only moderate mitral regurgitation. As the Trust does not contest that claimant had at least moderate mitral regurgitation, which is sufficient to qualify for a Level II claim, the only issue is whether claimant had a reduced ejection fraction.

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Cobb's claim.

"ejection fraction over 60% is associated with a hypercontractal state of the left ventricle. This is clearly not the case on the echo study of Ms. Cobb dated 2/4/2002." Claimant also submitted two letters dated August 16, 2002 and July 9, 2003, from her treating physician, Edward J. Morris, M.D., F.A.C.C., two myocardial perfusion imaging reports dated January 28, 2002 and August 12, 2002, and three echocardiogram reports for echocardiograms performed on December 3, 2002, June 27, 2003, and October 26, 2004. According to claimant, these studies demonstrate that there is a reasonable medical basis for Dr. Meshkov's Green Form representation because each one reports an ejection fraction of less than or equal to 60%.

The Trust issued a final post-audit determination, again denying Ms. Cobb's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Cobb's claim should be paid. On April 11, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6125 (Apr. 11, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on September 27, 2006.

Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁹ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had a reduced ejection fraction in the range of 50% to 60%. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

claim in accordance with the Settlement Agreement. See id.

Rule 38(b) .

In support of her claim, Ms. Cobb makes the same arguments she made in contest; namely, that there is a reasonable medical basis for Dr. Meshkov's Green Form representation that claimant had a reduced ejection fraction in the range of 50% to 60%.

In response, the Trust argues that, in any event, Dr. Meshkov's letter does not provide a reasonable medical basis for his Green Form representation because he states, without medical support, "that 'an ejection fraction over 60% is associated with a hypercontractal state of the left ventricle.'"¹⁰ In addition, the Trust asserts claimant cannot establish a reasonable medical basis for the attesting physician's Green Form representation at issue by referencing myocardial perfusion imaging studies or other echocardiograms.

The Technical Advisor, Dr. Vigilante, reviewed claimant's February 4, 2002 echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding that claimant had a reduced ejection fraction. Specifically, Dr. Vigilante determined that:

10. The Trust also argues that the supplemental letter from Dr. Meshkov is not permitted by the Audit Rules because it is unverified. We disagree. As we have previously stated, "[w]hile the Audit Rules allow for the submission of verified expert opinions, it does not preclude the submission of expert opinions that are not verified." PTO No. 7402 at 8 n.9 (Aug. 30, 2007) (citing Audit Rule 18(b)).

The left ventricular ejection fraction appeared to be 50 to 60% when evaluated in the parasternal long axis, parasternal short axis, apical four chamber, and apical two chamber views. I digitized those cardiac cycles in the apical views in which there was excellent endocardial definition of the left ventricle. I then electronically traced the endocardium of the left ventricle in end systole and end diastole and calculated the ejection fraction using Simpson's method. I determined that the ejection fraction was 54% using Simpson's method.

* * *

In response to Question 2, I determined that there is a reasonable medical basis for the Attesting Physician's answer to Green Form Question F.8. That is, I calculated the [c]laimant's ejection fraction to be 54% which is within the range of 50-60%.

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician, Dr. Meshkov, reviewed claimant's echocardiogram twice and found that claimant had a reduced ejection fraction in the range of 50% to 60%. Although the Trust challenged the attesting physician's finding, Dr. Vigilante confirmed Dr. Meshkov's finding of a reduced ejection fraction.¹¹ Specifically, Dr. Vigilante measured claimant's ejection fraction and "determined that the ejection fraction was 54% using Simpson's method." Under these

11. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.¹²

For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim and that she consequently is entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of Ms. Cobb's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

12. Accordingly, we need not address the Trust's argument that claimant cannot support a reasonable medical basis for Dr. Meshkov's Green Form representation by referencing myocardial perfusion imaging studies or other echocardiograms.